

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

5 In re application of: Carpentier, et al.) Group Art Unit: Unknown
Application No.: Unknown) Examiner: Unknown
Filed: Herewith)
10 For: APPARATUSES FOR TREATING BIOLOGICAL)
TISSUE TO MITIGATE CALCIFICATION)



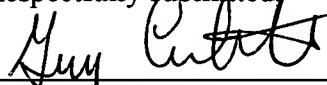
15 TRANSMITTAL LETTER ACCOMPANYING
INFORMATION SUBMISSION PURSUANT TO 37 CFR §1.56 AND MPEP §724

Assistant Commissioner of Patents
Washington, D.C. 20231

20 Dear Sir:

TRADE SECRET MATERIAL NOT OPEN TO PUBLIC.
TO BE OPENED ONLY BY EXAMINER OR OTHER AUTHORIZED PATENT
AND TRADEMARK OFFICE EMPLOYEE

Respectfully submitted,

30 
Guy Cumberbatch
Baxter Healthcare Corporation
Post Office Box 15210
35 Irvine, California 92623-5210
Telephone: (949) 250-6807
Facsimile: (949) 250-6850

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: S. Carpentier, et al.

Group Art Unit: Unknown

Application No.: Unknown

Examiner: Unknown

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For: APPARATUSES FOR TREATING
BIOLOGICAL TISSUE TO
MITIGATE CALCIFICATION



Assistant Commissioner of Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to the duty of disclosure set forth under 37 CFR §§ 1.56, 1.97(c), and 1.98, Applicants enclose the attached form PTO-1449. This submission is prior to receipt of a first Office Action on the merits and thus, pursuant to 37 CFR § 1.97(b)(3), no fee is believed due.

Pursuant to 37 CFR § 1.98(d), copies of the patents listed on the Form PTO-1449 are not provided as they were of record in parent case S/N 08/874,180. Applicants will, of course, provide copies if examiner requires.

The material submitted pursuant to MPEP §724 is provided, along with a Petition to expunge.

Date:

3/31/99

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Guy Cumberbatch".

Guy Cumberbatch, Reg. No. 36,114
Baxter Healthcare Corporation
Post Office Box 15210
Irvine, California 92623-5210
Telephone: (949) 250-6807

Docket No. ECV-4652CIP1DIV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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BIOLOGICAL TISSUE TO)
<u>MITIGATE CALCIFICATION</u>)

Assistant Commissioner of Patents
Washington, D.C. 20231

INFORMATION SUBMISSION PURSUANT TO 37 CFR §1.56 AND MPEP §724

Dear Sir:

This is to notify the Examiner in the above-referenced case of certain pre-filing activities of the Assignee which may be material under Rule 56. The activities comprise steps in tissue processing which are considered TRADE SECRETS.

For at least eight years the Edwards Cardiovascular division (now Heart Valve Therapy division) of Baxter International (the Assignee) has been processing fresh pericardial tissue for use in the manufacture and sale of bioprosthetic heart valves in the following way.

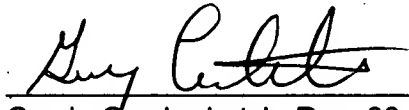
1. Trim fresh pericardial sac, then
2. Place individual pieces of fresh tissue in a container of glutaraldehyde, then
3. Shake the container in step 2 for 30 minutes, then
4. Remove the individual pieces of tissue from the container, then
5. Stack the individual pieces of tissue, then
6. Store the stacked pieces of tissue in solution of glutaraldehyde for 14 days.

Application Serial No.: Unknown
Filing Date: Herewith

After step 6, the individual pieces of trimmed tissue are subjected to a sterilization treatment and are then cut into leaflets and assembled into tissue valve.

The shaking of step 3 is for the purpose of stirring the solution and removing areas depleted of glutaraldehyde. The tissue pieces are thus surface-exposed to glutaraldehyde prior to steps 5 and 6. No heat is applied to the solutions in any of steps 1-6.

Respectfully submitted,



Guy L. Cumberbatch, Reg. 36,114
BAXTER HEALTHCARE CORPORATION
Post Office Box 15210
Irvine, California 92623-5210
Telephone: (949) 250-6807
Facsimile: (949) 250-6850

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